

## **REMARKS**

### ***Amendments to the Specification***

The specification has been amended at page 4 to recite embodiments wherein the fermentation substrate comprises more than 50 wt% soy ingredients and more than 80 wt% soy ingredients. Support is found in original claims 2 and 3.

The specification has been amended at page 10 to correct a typographical error pointed out by the office wherein a “%” symbol was inadvertently omitted.

### ***Amendments to the Claims***

Claim 19 has been amended and new independent claims 26 – 28 have introduced without prejudice to recite preferred embodiments of applicants invention whose metes and bounds are more definite and whose subject matter is more clearly distinguished from the prior art. No new matter has been introduced.

Support for claim 26, 27 and 28 is given on pages 4 and 19 of the specification as filed.

Claims 14, 21 and 24 have been amended without prejudice to make their metes and bounds more definite.

Claims 20 and 22 have been amended to make their enablement more clearly supported by the specification.

Claim 25 is hereby cancelled.

### ***The Present Invention***

The present invention is directed to food product incorporating a fermentation products made by fermenting soy bean ingredients with a statins producing fungus. Applicants have developed a fermentation process based on the use of substrates predominantly based on soy ingredients in combination with specific fungi and process additives that yields fermentation products containing statins and various “soy actives” such as polyphenols (e.g., isoflavones) which are useful in lowering serum cholesterol. Importantly, the extracts are intrinsically light in color in contrast to prior art fermentations and thus do not detract from the aesthetic properties of the food products in which the fermentation products are incorporated.

### ***Claims Rejection – 35 USC § 112***

Claim 11-16, 19-25 were rejected under 35 USC §112 first paragraph. The Office asserts that the specification, while being enabling for the Monascus species does not provide reasonable enablement for any fungus. The Office pointed out that on page 5, lines 5-18, the Monascus fungus is specified and asserted that no other is disclosed. Applicants respectfully disagree and draw the Examiners attention to Page 2, lines 11 -15 copied below:

"The production of statins is also reported in fermentation using fungi other than the above-mentioned *Monascus* species. It has been shown that statins can be produced by a variety of filamentous fungi, including *Monascus*, *Aspergillus*, *Penicillium*, *Pleurotus*, *Pythium*, *Hypomyces*, *Paecilomyces*, *Eupenicillium*, and *Doratomyces*."

Applicants' submit that this disclosure would enable one skilled in the art to which the invention pertains (e.g., a microbiologist skilled in fermentation) to practice the invention with other types of fungi even though *Monascus* is disclosed as a preferred fungus. Consequently, applicants respectfully request the 112 first paragraph rejection be reconsidered and withdrawn.

Claims 11-16, 19-23 and 25 were rejected under 35 USC §112 second paragraph as being indefinite. The following changes have been made.

Claim 19 has been amended to recite the specific soy ingredients recited in the specification on page 16, line 23 to page 17, line 9 as a Markush group which includes whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes.

Claim 21 has been amended to state that polyphenols comprise genistein and genistin.

Claim 24 has been amended to specify that the substrate comprises whole soybeans or crushed whole soybeans ("substantially consisting of" replaced by comprising).

Claim 14 has been amended to add a “%” sign after wt.

Claim 25 has been cancelled (subject matter incorporated in claim 19 – comma inserted between “bar” and “meal replacer”).

Claims 11-16 and 19-25 were rejected under 35 USC §112 first paragraph as failing to comply with the written description requirement. The following changes have been made:

Claim 19 and 22 have been amended to replace “at least 50%” by “more than 50%” and the specification has been amended at page 4 to include this limitation which was first disclosed in original claim 2.

Claim 20 has been amended to replace “at least 80%” by “more than 80%” and the specification has been amended at page 4 to include this limitation which was first disclosed in original claim 3.

### ***Claim Rejections - 35 USC § 102***

Claims 11-16, 19-21, 23, and 25 were rejected under 35 USC §102(b) as being anticipated by Japan patent JP-01277454 (JP-‘454). A translation of the patent is included with this response. Applicants respectfully submit that the invention is not anticipated by JP-‘454 because JP-‘454 does not disclose in a single reference all the elements recited in applicants claims.

JP-'454 is directed to improving the taste of seasoned meat-like protein material made from tofu (soybean curd). A part of the tofu is fermented with *Monascus* or *Mucor* or *Actinomucor*. Various treatments are disclosed that involve in addition to fermentation, dehydration, dipping into seasoning liquids, etc.

JP-'454 is silent about the presence or levels of statins or any soy actives in the fermentation product. For example, the words statins, polyphenols, saponins, polyunsaturated fatty acid esters, pytoserols do not appear in the publication.

JP-'454 is silent about the Hue  $a^*$  value of the fermentation product.

JP-'454 is silent about the use of the disclosed fermentation product in a food product selected from the group consisting of a margarine, a dressing, a sweet, a bar, a meal replacer, a breakfast cereal and a beverage.

The Office asserts that the Hue  $a^*$  value, statins and polyphenols recited in applicants claims would be essentially inherent in the JP-'454 fermentation product because the same fungus and substrate were used. Applicants respectfully disagree.

Applicants submit that a fermentation process is a chemical reaction and thus the products formed will depend on the reaction conditions and the reagents employed and thus are not intrinsic with respect to only the starting materials. Such variability is indeed disclosed in JP-'454 regarding the color of the fermentation product. Specifically, it is stated on page 9 (3<sup>rd</sup> paragraph) that "As compared with No 5 of Example 1, the protein material using Funi made in Taiwan was a bit brownish but anyway, all were in good taste and palatability and showed very little loss of taste upon biting". Thus, some of the conditions employed in JP-'454 lead to brownish fermentation products which would

no doubt have a Hue a\* value >20 and be unacceptable for the applications to which applicants' invention is directed.

Furthermore there is no evidence that any of the fermentation conditions employing the reagents (seasonings) and treatments recited in JP-'454 (e.g., dipping in Sake, Miso, dehydration and compaction) would lead to formation of any statins or polyphenols.

In contrast, applicants' claim 19 is directed to food products selected from the group consisting of a margarine, a dressing, a sweet, a bar, a meal replacer, a breakfast cereal and a beverage that contains a fermentation product that must comprise one or more statins and one or more polyphenols and must have a Hue a\* value less than 20. Since, four key elements (food type, statins, polyphenols, and Hue a\* value) are not disclosed in JP-'454, applicants' submit that claim 19 is not anticipated by JP-'454.

Applicants submit that Claims 11-16, 21-24 and 26-28 are even more removed from JP-'454 as none of the key elements and limitations recited in the following claims are disclosed in JP-'454.

Claim 11 – 16 amounts of statins, genistein and genistin, polyphenols and Hue a\* value less than 10

Claim 21 – critical wt% genistein

Claim 22 – Fermentation in the presence of 10% vegetable oil

Claim 24 – substrate whole soybeans or crushed soybeans

Claim 26 – incorporation of an extract of the fermentation product

Claim 28 – vegetable oil extract

In view of the amendments and above remarks, applicants respectfully request that the 102(b) rejection over Japan patent JP-01277454 be reconsidered and withdrawn and that the application be allowed to issue.

Claims 11-16 and 19-25 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of US Patent No 8,849,281. In view of the availability of Terminal Disclaimer Practice, applicants agree to file a Terminal Disclaimer on an indication of allowable subject matter.

If a telephone conversation would be of assistance in advancing prosecution of the subject application, applicants' undersigned agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael P. Aronson".

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## LAID-OPEN PATENT GAZETTE, JAPANESE PATENT OFFICE (JP) (A)

**Laid-Open Number:** 01/277,454**Laid-Open Date:** 07 November 1989**Application Number:** 63/105,773**Application Date:** 28 April 1988**Int. Cl. 4:** A 23 J 3/00**Inventors:** Yoshiaki Ueki and Masahiko Terashima**Applicant:** Fuji Oil Co., Ltd.

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## METHOD FOR MANUFACTURE OF SEASONED PROTEIN MATERIAL

Claims

1. A method for the manufacture of a seasoned protein material where protein material and *furyu* are subjected to an extrusion cooking in an aqueous system.

Detailed Description of the Invention

## Technical Field of the Invention

The present invention relates to a method for the manufacture of seasoned protein material where loss of taste by biting is very little and taste is good even in a cool state.

## Prior Art

Up to now, many inventions concerning meat-like protein materials have been done. One of the popular methods for the manufacture thereof is an extrusion cooking. In the meat-like protein material, that which is seasoned as it is has been rare because it is subjected to a secondary seasoning according to the particular use.

However, when food mainly comprising the meat-like protein material itself (such as *karaage* [deep-fried food without or only a little coating] and beefsteak) has become to be eaten in recent years by consumers,



there has been a demand for a meat-like protein material which has a good taste as it is.

In a method for seasoning the meat-like protein material, there has been known a primary seasoning (in which a seasoning is compounded with a crude protein material to prepare a protein material) in addition to the secondary seasoning (in which protein material is seasoned) and, in the seasoned protein material prepared by prior art, there is a problem that taste is quickly lost upon biting.

Incidentally, *funyu* is one of fermented foods prepared from *tofu* (soybean curd) and has been eaten in China and in Taiwan. In China for example, *tofu* is used as a starting material, its water content is adjusted usually by dehydration and mould is grown thereon, dipped in a seasoning liquid or the like and aged to prepare *funyu*. In Taiwan, *tofu* is usually used as a starting material, water content therein is adjusted usually by dehydration to enhance the shape-holding property of *tofu* and then dipped in solution of *koji* [a preparation obtained by growing a kind of mould such as *Aspergillus niger* - Translator] (such as a solution of rice *koji* and bean *koji*) followed by aging to prepare *funyu*. "*Tofuyo*" is a traditional *funyu* in Okinawa Prefecture and is prepared in such a manner that water content of *tofu* is reduced (usually to an extent of about 50%) by drying in the sun to give a shape-holding property and dipped in a *koji* solution (rice *koji* and "*awamori*" which is a kind of *shochu* (distilled wine) made in Okinawa)) followed by aging. In Gokanoshio of Fukuoka Prefecture, "*tofu* dipped in *miso* (soybean paste)" has been known. It is prepared in such a manner that water content of *tofu* is reduced by, for example, heating with fire to give a shape-holding property and dipped in *miso* in which *koji* is grown in soybean, barley, washing of rice, etc. followed by aging.

However, no method where a protein material is manufactured using *funyu* has been known yet.

#### Problems that the Invention is to Solve

As mentioned already, even when a protein material is seasoned (either by a primary seasoning or a secondary seasoning), there is a problem of loss of taste upon biting. In addition, when the product is made into *karaage* or the like, although the fried thing has a good taste when it is hot, there is a problem that taste is greatly deteriorated when it becomes cool.

### Means for Solving the Problems

The present inventors have conducted intensive studies for solving the above-mentioned problems, checked many seasonings and seasoning materials and found that the above problems are able to be solved when *funyu* is used whereupon the present invention has been achieved.

Thus, the present invention relates to a method for the manufacture of a seasoned protein material where protein material and *funyu* are subjected to an extrusion cooking in an aqueous system.

With regard to the protein material used in the present invention, one or more member(s) selected from protein prepared from soybean, rapeseed, peanut, etc., protein prepared from cereal such as gluten, other plant protein and animal protein obtained from casein, egg white, bird, fish, shellfish, etc. is/are used.

The *funyu* used in the present invention is a fermented food where *tofu* is a starting material and, during the process of fermentation and aging, mould such as *koji* is participated in that. Its preferred examples are (1) a product where mould is made to generate on *tofu* and aged by dipping in a seasoning liquid and (2) a product where *tofu* is dipped in a *koji* solution followed by aging. Examples of the manufacturing method the former are that in China, etc. while examples of manufacturing method for the latter are that in Taiwan, Okinawa Prefecture and Gokanoshio (Kumamoto Prefecture). The *funyu* may also be used either by drying or by pulverizing.

The *tofu* used for *funyu*, a soybean protein curd which is prepared from soybean protein and fat/oil together, if necessary, with alkali earth metal salt may be used in addition to the common *tofu* (commercially available *tofu*) manufactured from soybean or defatted soybean by a conventional method. When mould is grown on *tofu* followed by dipping in a seasoning liquid or when *tofu* is dipped in a *koji* solution without generation of mould, it is preferred to dehydrate or dry to adjust the water content so that mould is apt to be generated whereby *tofu* has a shape-holding property and is not polluted with other microbes. Water content is usually preferred to be 50 to 80%.

Mould to be grown on *tofu* is usually that belonging to genus *Monascus*, genus *Mucor*, genus *Rhizopus*, genus *Actinomucor* or the like. The *tofu* which is enclosed by hyphae of mould (preferably before formation of spores) is pickled if necessary and then dipped in a seasoning liquid.

With regard to a seasoning liquid, that where rice wine, salt and spice are main components may be used. It is likely that alcohol in rice wine and salt prevent the putrefaction during the aging and that mould

generated in *tofu*, other microbes and seasoning liquid give good taste and texture to the *tofu* during the aging. It is also possible to use pink *koji* (*Monascus anka*) for colouration.

With regard to the *koji* liquid into which *tofu* is dipped, it is possible to use *koji* of cereal such as soybean *koji*. Thus, the *koji* liquid is prepared in such a manner that rice, barley, soybean or like is steamed and *koji* microbe (mould of genus *Aspergillus*) is planted thereon followed by fermenting according to a known method. In the case of rice *koji*, the liquid is mostly abundant in saccharide and alcohol being sweet and tasty while, in the case of soybean *koji*, the liquid is mostly abundant in amino acids and tasty. The *tofu* is aged in the *koji* liquid as such.

Period for the aging after dipping in a seasoning liquid or a *koji* liquid is able to be adjusted depending upon the preference. Not longer than one year is sufficient and, usually, it is appropriately to be one month to a half year.

The *funyu* which is prepared after the aging is a soft and cheese-like smooth fermented food containing 50 to 80% of water and has specific smell and strong taste. Incidentally, *funyu* is also called Chinese cheese. In the traditional *funyu*, free amino acid content is usually 10 to 20% and non-protein nitrogen in total nitrogen is usually 30 to 80% (in many cases, it is 50 to 70%). There is a tendency that amount of directly reduced sugar is low and that colouration due to Maillard reaction during compressing and heating in an extrusion cooking is little in a product dipped in a seasoning liquid mainly comprising Japanese *sake* than the product dipped in a *koji* liquid during the aging. Accordingly, the above methods may be appropriately selected depending upon the aimed protein material.

Amount of the *funyu* used varies depending upon the aimed protein material, rate of protein material to other materials, degree of swelling, etc. whereby, although there is no particular limitation for the amount, it is appropriate when a protein material which is texturized and swollen by an extrusion cooking is an aimed product that the amount of *funyu* (containing 50 to 80% of water) to 100 parts by weight of materials (excluding water) is not less than 1 part by weight or, preferably, 5 to 30 parts by weight. Although the outcome depends upon the degree of aging of *funyu*, 1 part by weight or more of *funyu* is able to give a product which does not lose its taste even by biting, has a good taste even in a cool state and is most suitable as a protein material. When a protein material of a swollen type is aimed, there is a tendency that the swelling is disturbed when the amount of *funyu* is more than 30 parts by weight. In the case of a lowly swelling type or a non-swelling type (such as in a sheet form), texturizing is still possible even

by the use of about 50 parts by weight although that depends upon the heating time in the extrusion cooking.

As to other materials, it is possible to use cereal, cereal powder, other starch material, polysaccharide derived from *okara* (bean-curd leavings) and other cereals, polysaccharide derived from seaweed and microbe, gum substance, etc. together therewith. Starch has an effect of assisting the swelling and making the texture smooth. Polysaccharide and gum substance have an effect of improving the texture. It is also possible to use fat/oil and fat/oil-containing emulsion (regardless of water-in-oil type and oil-in-water type). Particularly when an extrusion cooking is conducted by a biaxial extruder, it is possible to easily prepare a protein material of a swelling type even if oil is contained in the starting material whereby there is an effect of improving the palatability by fat/oil.

The term of "in an aqueous system" in the present invention means that the starting material in a state of containing water is subjected to an extrusion cooking. Water may be that derived from *fuzuyu*, soybean milk, plant extract, etc. besides common water. Addition of water may be also conducted before or during the extrusion cooking.

Water amount may be usually in 10 to 80% by weight in the starting material although that may depended upon the aimed particular protein material. In the present invention, known extruders may be used in the extrusion cooking and extrusion may be done under compressing and heating. There is no problem whether a uniaxial extruder is used or a multi-axial extruder of biaxial and more multi-axial one is used. When the aimed protein material is intended to give more meat-like texture and palatability, a biaxial and more multi-axial extruder is preferred since a protein material having a good fibrous structure is able to be prepared by that. In texturization of the case where oil is contained in the starting material, the use of biaxial or more multi-axial extruder is preferred.

Degree of pressurization may be usually about 0.5 to 100 kg/cm<sup>2</sup> near the outlet of an extruder.

Degree of heating may be usually about 80 to 250°C near the outlet of an extruder. There is no limitation whether the area near the outlet is cooled or not.

With regard to a die or an orifice of the extruding outlet, known ones may be used. Direction for extrusion may be the same as that of screw or may be in a centrifugal direction as in the case of peripheral die. It is possible to select the shape of the outlet die or the orifice depending upon the object. Known ones such as single hole, plural holes, mesh-form one, long-die-form one, etc. may be used.

## Examples

The present invention will now be illustrated by way of the following Examples.

### Example 1

Protein materials were manufactured according to the compounding of the starting materials as shown in Table 1.

Table 1: Compounding of Starting Materials (unit: part(s) by weight)

Nos.	1	2	3	4	5	6
Separated soybean protein	65	65	65	65	65	65
<i>Okara</i> (Soybean-curd leavings)	20	20	20	20	20	20
Wheat gluten	10	10	10	10	10	10
Starch	5	5	5	5	5	5
Soybean sauce	5	—	—	—	—	—
<i>Funyu</i>	—	3	6	10	20	30
Salt	1	1	1	1	1	1
Seasoning	1.5	1.5	1.5	1.5	1.5	1.5

With regard to the *funyu* (containing 70% of water), that which was made in China was used. With regard to the seasoning, HVP (= hydrolysed vegetable protein) was used.

The starting materials were supplied to a biaxial extruder (L/D = 14.4) under such a condition that a control was done so that about 30 parts by weight of water (including water in the *funyu*) was contained in 100 parts by weight of the starting materials (excluding water in the *funyu*), extruded from a round die (5 mm  $\phi$ ) where the front end temperature of barrel was 150°C and screw rotation was 250 rpm and continuously cut using a cutter to give a granular texture of protein material of 10 to 20 mm  $\phi$ .

Each of the dried protein materials was reconstituted with 6-fold of hot water, water was lightly strained so as to make into a state of about 3-fold water was contained and tests were conducted for taste or loss of the taste by biting.

The result is shown in Table 2.

Table 2

Nos.	Taste	Smell	Palatability	Loss of Taste
1	o	o	o	x
2	Δ	o	o	Δ
3	o	o	o	o
4	o	o	o	o
5	o	Δ	o	o
6	o	Δ	Δ	o

In the taste:—

Δ: the taste is a bit weak

o: the taste is strong and good

In the smell:—

Δ: some specific smell was noted but it was not unpleasant

o: slight specific smell was noted but it rather stimulates appetite

In palatability:—

Δ: texture was sometimes unstable and palatability was sometimes weak as well

o: meat-like palatability was available

In loss of the taste:—

x: the taste was soon lost upon biting

Δ: upon biting, loss of the taste was little but the taste was a bit weak

o: even upon biting, the taste was hardly lost and good taste was maintained

#### Example 2

Protein materials were prepared by the same manner as in Example 1, reconstituted with hot water the same as therein as well, battered with a batter liquid where commercially available flour for frying was kneaded with cold water (1:1.2 by weight/weight) and fried in a frying oil of 170 to 180°C for 1 minute and 20 seconds to give *karaage*.

The resulting *karaage* was wrapped to avoid evaporation of moisture and allowed to stand for 24 hours. This will be called group A.

After that, another *karaage* was prepared the same as above and will be called group B.

Sixteen panellists were asked to compare the groups A and B in their tastes.

The result is shown in Table 3.

Table 3: Numbers of Panellists Answered for the Comparison of  
Group A with Group B

Nos.	No change in Taste	Taste became better	Taste became worse
1	4	1	11
2	6	1	9
3	8	2	6
4	8	4	4
5	5	6	5
6	4	7	5

Thus, as compared with No. 2, deterioration in the taste in Nos. 2 to 6 was very little in the group A as compared with the group B.

#### Example 3

Protein materials were manufactured by the same manner as in No. 5 of Example 1 using *funyu* which was made in Taiwan, which was "*tofuyō*" made in Okinawa Prefecture and which was "*tofu* dipped in soybean paste" made in Gokasho.

As compared with No. 5 of Example 1, the protein material using *funyu* made in Taiwan was a bit brownish but, anyway, all were in good taste and palatability and showed very little loss of the taste upon biting.

Another *karaage* was prepared in the same manner as in Example 2 and palatability and taste in the cool state were tested whereupon it was found the product was in good taste even in the cool state.

#### Advantages of the Invention

As fully illustrated hereinabove, in accordance with the present invention, it is now possible in accordance with the present invention to manufacture a seasoned protein material where loss of taste upon biting is little and taste is good even in a cool state.

[ End ]